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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,181	11/10/2000	Steven D. Jensen	7678.350.2	4245

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/710,181	JENSEN ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41,42 and 44-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,42 and 44-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The prosecution of the application has been reopened in light of an IDS filed by the Applicants on 7/30/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 41,42,44-51,53 and 55-73 are rejected under 35 U.S.C. 102(e) as being anticipated by McLaughlin (USPN 6108850; 8/29/00).

McLaughlin teaches a composition for whitening teeth comprising a bleaching agent such as 10% hydrogen peroxide and an agent for reducing tooth sensitivity such as 1% potassium nitrate. See column 4 lines 5-12, column 7 Example 4. McLaughlin teaches bleaching agents other than hydrogen peroxide (e.g. 10 to 40% carbamide peroxide or carbamyl peroxide) can be used in the composition. See column 2 line 15 –

column 3 line 7. McLaughlin teaches that the composition can further comprise water , polyethylene glycol (see column 2 line 64 – column 3 line 7), xantham gum (column 3 lines 38—61) and stannous fluoride (column 3 line 62 - column 4 line 4). McLaughlin teaches a method of applying the composition to teeth for the purpose of whitening teeth. McLaughlin teaches that the composition can be applied using a dental tray. See column 4 line 59 - column 5 line 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 52,54 and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimada et al (USPN 5626837; 5/6/97) in view of McLaughlin as applied to claims 41,42,44-51,53 and 55-73 above. McLaughlin teaches all that is recited in claims 52,54 and 74-76 except for the invention comprising an antimicrobial agent such as cetyl pyridinium bromide and stabilizer such as citric acid as well as the length of time the teeth are subjected to dental tray application. However, Shimada et al teach dental compositions (toothpaste, mouthwash, etc.) comprising antimicrobial agents such as cetyl pyridinium chloride, pH adjustors such as citric acid, actives such as stannous fluoride and humectants such as polyethylene glycol (see abstract, column 1 lines 17- 42, column 3 line 57 – column 4 line 31). It would have been obvious to one having ordinary skill in the art to modify the invention of McLaughlin to include the cetyl

pyridinium halide and the citric acid taught by Shimada et al. One would have been motivated to do this since both inventions are to dental / oral compositions for the protection and healthy maintenance of teeth. In addition one would have been motivated to do this in order to protect the teeth and gums from bacterial infection, and one would have been motivated to employ citric acid in order to adjust the pH of the composition to a stable environment. With respect to the time length of applying the dental tray to the teeth, one having ordinary skill in the art would have been motivated to determine the optimum time range in order to obtain the best result of whitening and protecting teeth.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41,42,44-87 are no longer rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,10,11,13-26 of U.S. Patent No. 6309625. Although the conflicting claims are not identical, they are not patentably distinct from each other because Fischer claims (USPN 6309625) a

composition comprising peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-50 % potassium nitrate. The composition can further comprise 0.5-20 % carboxypolymethylene, 20-85% polyol such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. Applicant's specification (USPN 6309625) teaches that the amount of peroxide ranges from 0.5-50 %. See column 9 lines 40-54. Fischer's invention (USPN 6309625) also claims a method to bleaching teeth with the composition with the aid of a tray. Fischer's invention (USPN 6309625) discloses amounts of potassium nitrate (0.1-50 %) and peroxide (0.5-50 %), which encompass instant amounts of potassium nitrate and peroxide. Fischer's invention (USPN 6309625) also claims a method to bleaching teeth with the composition with the aid of a tray. For this reason, it would have been obvious to one having ordinary skill in the art at the time the prior art invention was made to employ the instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the USPN 6309625 amounts overlap the instant amounts. Applicant points out in a declaration and a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, the Examiner argues that the declaration is not commensurate in scope with claims because the claims recite a range of 0.5-50% peroxide and applicants' declaration only shows results for ranges of peroxide being 10% or 15%.

Response to Applicants' Argument

Rejection of claims 41,42,44-87 over obviousness-type double patenting with respect to USPN 6309625 will not be maintained. Applicants are correct in that the claims in USPN ' 625 makes no suggestion to dental bleaching composition comprising 0.5 to 50% peroxide.

Claims 41,42,44-76 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306370. Although the conflicting claims are not identical, they are not patentably distinct from each other because Fischer (USPN 6306370) claims a composition comprising 3-20 % peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-10 % potassium nitrate. The composition can further comprise carboxypolymethylene, polyols such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. Fischer's invention (USPN 6306370) also claims a method to whitening (bleaching) teeth with the composition with the aid of a tray. Fischer's invention (USPN 6306370) discloses amounts of potassium nitrate (0.1-10 %) and peroxide (3-20 %), which encompass instant amounts of potassium nitrate and peroxide. Fischer's invention (USPN 6306370) also claims a method to bleaching teeth with the composition with the aid of a tray. For this reason, it would have been obvious to one having ordinary skill in the art at the time the invention (USPN 6306370) was made to employ the instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the USPN 6306307 amounts overlap the instant amounts. Applicant points out in a declaration and

a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, the Examiner argues that the declaration is not commensurate in scope with claims because the claims recite a range of 0.5-50% peroxide and applicants' declaration only shows results for ranges of peroxide being 10% or 15%.

Response to Applicants Argument

Rejection of claims 41,42, 44-87 over obviousness-type double patenting with respect to USPN 6306370 will be maintained for reason on record and reason as follows.

Applicants make several arguments as to why the rejection should be withdrawn. Applicants provide declarations to support their position. Applicants also point out that a double patenting rejection is over the claims not the body of the disclosure.

The Examiner agrees with the point made by the Applicants that a double patenting rejection is over the claims not the body of the disclosure. It is for that very reason the double rejection over USPN '370 is maintained.

A) Note that Applicants' claims are to a dental bleaching composition comprising:

1) about 0.5 to about 50 % peroxide as to have a tooth bleaching effect;

2) about 0.01 to about 2 % potassium nitrate as to result in reduced tooth sensitivity that may be caused by the peroxide; and

3) a carrier.

B) Note that USPN '370 makes claim (see claim 14) to a dental bleaching composition comprising:

1) about 3 to about 20% peroxide;

2) about 0.01 to about 10% potassium nitrate in an amount to reduce tooth sensitivity that may be caused by the peroxide; and

3) a carrier.

In the comparison of Applicants' claims with USPN '370 claims, the claims in USPN '370 makes obvious instant claims. Note instant claims to composition comprising about 0.5% to about 50 % peroxide encompasses instant peroxide range of about 3% to about 20% peroxide. Note that instant claims to composition comprising about 0.01 to about 2 % potassium nitrate fall within the range (about 0.01 to about 10%) claimed in USPN '370. Therefore, USPN '370 claims makes obvious the instant claims. Applicants provide unexpected for a composition comprising 10 or 15 % peroxide and 0.5 % potassium nitrate (see evidence appendix). As recited in office action of 4/5/2005, the Examiner agrees that results are convincing as well as unexpected. However, the Examiner maintains that the claims are not commensurate in scope with the claimed range of peroxide being about 0.5 to about 50%. Note that Applicants instant claimed range of peroxide is boarder than the range claimed in USPN '370. For this reason, the rejection is maintained. Applicants argue that the criticality of

the invention lies within the amount of potassium nitrate not in the amount of peroxide. This may be true, however, this statement is not convincing since Applicants only provide data for 10% and 15% peroxide in the broad range of about 0.5 to about 50% peroxide instantly claimed. For the above reasons USPN '370 is cited as an obviousness-type double patenting rejection over instant claims. To maintain clarity that the obviousness type double patenting rejection is maintained due to claimed subject matter in instant claims versus claims in USPN '370, arguments with respect to Examples 7 and 14 in USPN '370 will not be entertained.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/

Primary Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616